UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated, Plaintiffs, v. BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendants.	Civil Action No. **CLASS ACTION** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer" or "Plaintiffs") on behalf of themselves and all others similarly situated, for their Complaint against Defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, "Boehringer" or "Defendants"), allege as follows based on (a) personal knowledge, (b) the investigation of counsel, including review of pleadings and court orders in patent infringement and other litigation concerning the conduct at issue in this action, and (c) information and belief.

I. INTRODUCTION

1. This litigation arises from a series of actions undertaken by Defendants to unlawfully maintain their monopoly on Mirapex®. Faced with the threat of losing market exclusivity, Defendants engaged in a series of anticompetitive and unlawful actions that ultimately extended their monopoly on the sale of Mirapex®. But for Defendants' unlawful actions, generic versions of Mirapex® would have been available no later than May 8, 2007 – the date Boehringer's original patent purportedly covering Mirapex® expired. As alleged below, Defendants engaged in sham

litigation and entered into anticompetitive agreements to improperly maintain their monopoly profits in the market for Mirapex® and its AB-rated generic equivalents ("the Drug"), to the detriment of Plaintiffs and the Class of direct purchasers.

2. Generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between brand name drugs and generics is their price. Generics typically cost at least 30 percent less than their brand counterparts when there is a single generic competitor, and at least 80 percent less when there are multiple generic competitors on the market. As a result, generics constitute both an opportunity for drug purchasers and consumers to obtain enormous savings, and a threat to the monopoly power and profits of the brand name drug facing generic competition. Indeed, generics typically take 90 percent of the sales from the brand name manufacturer within a year of entry.

3. Acutely aware of these economic realities in the pharmaceutical industry, Defendants embarked on a scheme to maintain the monopoly profits generated by their control of the market for the Drug, and to eliminate the threat of competition from lower-cost generic substitutes.

4. Mirapex® is a branded prescription drug used to treat Parkinson's disease and Restless Leg Syndrome. The active pharmaceutical ingredient in Mirapex® is pramipexole dihydrochloride ("pramipexole" or "pramipexole products"). Defendants have manufactured and sold Mirapex® since 1997 and, since that time, have reaped monopoly profits on Mirapex®. Mirapex® has annual U.S. sales of approximately $380 million.

5. At least three manufacturers of generic drugs – Barr Pharmaceuticals, Inc. ("Barr"), Mylan Pharmaceuticals, Inc. ("Mylan") and Alembic Limited ("Alembic") – developed generic

versions of Mirapex® to sell in competition with Boehringer's product. In their applications, these three manufacturers asserted that their products were bioequivalent to Mirapex® and did not infringe on any valid patent owned or licensed by Defendants. Because of Defendants' actions, however, no generic formulation of pramipexole has reached the market.

6. To preserve its monopoly position, Defendants raised several barriers and unlawfully prevented competition from generic drugs that would have lowered prices for the Drug including, but not limited to, the following:

(a). obtaining U.S. Patent No. 4,886,812 ("812 Patent"), which Defendants knew or should have known was invalid because the patent claimed the same compound for which Boehringer had already received patent protection in U.S. Patent No. 4,834,086 ("086 Patent");

(b). listing the '812 Patent in the Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") to raise entry barriers;

(c). knowingly seeking a five-year extension of the invalid '812 Patent;

(d). suing both Barr and Mylan in the United States District Court for the District of Delaware for allegedly violating this invalid patent with their generic versions of the Drug to keep them off the market;

(e). waiting until the close of the evidence and just prior to closing arguments in its baseless patent infringement litigation – nineteen (19) months after the expiration of the '086 Patent – to attempt to terminally disclaim the '812 Patent, in an attempt to avoid the inevitable judicial determination that the '812 Patent was, in fact, invalid for

nonstatutory double-patenting;

(f). on June 26, 2008, despite knowing that its claims were meritless, appealing the Delaware District Court's decision finding that the '812 Patent was invalid and that its late terminal disclaimer was ineffective, when Defendants lacked an objectively reasonable basis to do so, solely to keep generic versions of Mirapex® from the market;

(g). notwithstanding the Delaware District Court's ruling that the '812 Patent was invalid, filing an additional lawsuit in January 2009 in the United States District Court for the District of New Jersey, alleging that Mylan had infringed its invalid '812 Patent; and

(h). on June 10, 2009, filing a notice of appeal of the New Jersey District Court's Order in May 2009 granting Mylan's motion to dismiss the litigation.

7. After the Delaware District Court declared the '812 Patent invalid, Defendants conspired with Barr to further restrain trade and guarantee Defendants' unlawful monopoly power in the market for the Drug by entering into an agreement whereby Barr: (a) would not contest the appeal; and (b) would not launch a competing pramipexole product until January 2010. In return, Barr received, among other things, valuable supply and co-promotion agreement to launch an authorized generic version of another of Defendants' drug, Aggrenox®.

8. The combination of the litigation appeal and the conspiratorial agreement with Barr was designed to, and has had the effect of, further, postponing the entry of a generic version of Mirapex® into the market by delaying Barr's generic launch, which serves as a bottleneck blocking other generic manufacturers (such as Mylan and Alembic) from entering.

9. As a result of Defendants' anticompetitive conduct, purchasers have been denied the

benefits of free and unrestrained competition. More specifically, Plaintiffs and the Class have been denied the opportunity to choose between brand name Mirapex® and lower-priced generic versions and have been made to pay supracompetitive prices for the Drug.

II. JURISDICTION AND VENUE

10. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit, reasonable attorneys' fees, for the injuries sustained by Plaintiffs and members of the Direct Purchaser Class resulting from Defendants' unlawful foreclosure of the market for Mirapex® and its AB-rated generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

11. Each Defendant transacts business within this District, and each carries out interstate trade and commerce, in substantial part, in this District. Venue, therefore, is appropriate within this District under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c). Venue is also appropriate with respect to Defendant Boehringer Ingelheim International GmbH under 28 U.S.C. §1391(d).

III. PARTIES

12. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. are corporations organized under the laws of the State of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the Class Period, as defined below, purchased Mirapex® directly and sold Mirapex® to Meijer and was injured as a result of Defendants' misconduct.

13. Defendant Boehringer Ingelheim International GmbH is a German limited partnership

with its principal place of business at Binger Straße 173, 55216 Ingelheim, Germany.

14. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

15. Defendants' actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

IV. CO-CONSPIRATORS

16. Other corporations, organizations, firms and individuals, including, *inter alia*, Barr, participated as co-conspirators in the violations alleged herein, and performed acts in furtherance thereof.

V. INTERSTATE COMMERCE

17. Defendants' efforts to monopolize and restrain competition in the market for the Drug have substantially affected interstate and foreign commerce.

18. At all material times, Defendants manufactured, promoted, distributed and sold substantial amounts of Mirapex® in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

19. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Mirapex®.

20. In furtherance of their efforts to monopolize and restrain competition in the market for the Drug, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were

within the flow of and have substantially affected interstate commerce.

VI. MONOPOLY POWER AND MARKET DEFINITION

21. At all relevant times, Defendants had monopoly power over the Drug, because they had the power to maintain the price of Mirapex® at supracompetitive levels profitably, without losing substantial sales.

22. A small but significant, non-transitory price increase of Mirapex® by Defendants would not have caused a significant loss of sales to other products.

23. Mirapex® does not exhibit significant, positive cross-elasticity of demand, with respect to price, with any product other than AB-rated generic versions of Mirapex®.

24. Because of, among other reasons, its safety and efficacy profile, Mirapex® is differentiated from all products other than AB-rated generic versions Mirapex®.

25. Defendants needed to control only Mirapex® and its AB-rated generic equivalents, and no other products, in order to maintain the price of Mirapex® profitably at supracompetitive levels. So while the market entry of a competing, AB-rated generic version of Mirapex® would render Defendants unable to profitably maintain their current prices of Mirapex® without losing substantial sales, the existence of or entry onto the market of no other drug product would render Defendants so unable.

26. Defendants also sold Mirapex® at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

27. Defendants have had, and exercised, the power to exclude competition to Mirapex®.

28. Defendants at all relevant times enjoyed high barriers to entry with respect to Mirapex®.

29. To the extent that defining a relevant product market is necessary in this case, the relevant product market is Mirapex® and its AB-rated generic equivalents.

30. The relevant geographic market is the United States.

31. At all relevant times, Defendants held a 100% share in the relevant product market in the United States.

VII. MARKET EFFECTS

32. The acts and practices of Defendants had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Mirapex® from generic competition. Defendants' actions allowed Defendants to maintain a monopoly and exclude competition in the market for the Drug, to the detriment of Plaintiffs and all other members of the Direct Purchaser Class.

33. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Mirapex® without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Mirapex® much sooner than they actually will be marketed, and, at all events, would have been on the market no later than May 8, 2007.

34. The generic manufacturers seeking to sell generic Mirapex® had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products.

35. Defendants' illegal acts to delay the introduction into the U.S. marketplace of any generic version of Mirapex® caused Plaintiffs and the Class to pay more than they would have paid for the Drug, absent Defendants' illegal conduct.

36. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand-name drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

37. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiffs, would have paid less for the Drug by (a) substituting purchases of less-expensive AB-rated generic Mirapex® for their purchases of more-expensive branded Mirapex® (i.e., brand-generic overcharges), (b) receiving discounts on their remaining branded Mirapex® purchases (i.e., brand-brand overcharges), and (c) purchasing generic Mirapex® at lower prices sooner (i.e., generic-generic overcharges).

38. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Mirapex®.

39. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

40. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Mirapex® from Defendants. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for the Drug. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Mirapex® was artificially inflated by Defendants' illegal conduct and/or (2) class members were deprived of the opportunity to purchase lower-priced generic versions of Mirapex® sooner.

41. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

IX. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand name Drugs

42. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

43. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act. Pub. L. No. 98-417, 98 Stat.1585 (1984) ("Hatch-Waxman"). The purpose of Hatch-Waxman was to hasten the delivery of inexpensive generic drugs to the market while respecting the patent rights of brand name drug patent holders.

44. Typically, generic versions of brand name drugs are priced significantly below their brand name counterparts. Because of the price difference and other institutional features of the pharmaceutical market, in every state pharmacists are permitted (and in some states, required) to automatically substitute the generic product for a brand name product unless the doctor has stated that the prescription for the brand name product must be dispensed as written.

45. As additional generic manufacturers enter the market, prices for generic versions of a drug decrease predictably because of competition among generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates. Generic competition enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price, and (b) purchase the brand name drug at a reduced net price.

46. Until a generic manufacturer enters the market, there is no bioequivalent generic drug that can substitute for the brand name drug, and therefore the brand name manufacturer can charge supracompetitive prices profitably without material loss to sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the introduction of generic competition into the market.

47. Hatch-Waxman represents a significant effort by Congress to hasten the delivery of generic drugs to the market. The principal mechanism Congress used was to eliminate the need for generic manufacturers to file a lengthy and costly NDA to obtain FDA approval for generic substitutes. Instead, under Hatch-Waxman, to obtain approval, the generic manufacturer is permitted to file an ANDA that incorporates the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA and then show only that the proposed generic drug is bioequivalent to the brand name drug, *i.e.*, that the generic drug contains the same active

ingredient(s), dosage form, route of administration, and strength as the brand name drug.

48. Once bioequivalence is demonstrated, the FDA assigns an "AB" rating to the generic drug, permitting it not only to be sold, but also to be substituted (and in some instances, *required* to be substituted), for the brand name drug at the pharmacy counter.

49. To protect brand name manufacturers' ability to enforce their patents against infringement through the ANDA process, Hatch-Waxman also streamlined the patent enforcement process, providing that the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months if the patent holder initiated a patent infringement lawsuit against the ANDA applicant.

50. When the FDA approves a brand name manufacturer's NDA, Hatch-Waxman allows the brand manufacturer to list in the FDA' s book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents.

51. The FDA plays only a ministerial role in Orange Book listings. The FDA relies completely on the brand name manufacturer for information concerning the validity of the patents and applicability of the patents to the brand name drug. The FDA does not check the representations supplied by the brand name manufacturer independently for accuracy or trustworthiness.

52. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

53. If a generic manufacturer files Paragraph I or II certifications, the FDA must act on the application within 180 days of receipt. If a generic manufacturer files a Paragraph III certification, the FDA can proceed with the ANDA approval process, with final approval being granted after the expiration of the applicable patents.

54. If a generic manufacturer files a Paragraph IV certification, however, a brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. Specifically, if the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. During the pendency of the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would qualify for final approval but for the 30-month stay, but cannot authorize the generic manufacturer to go to market. Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay the date of final approval of the generic drug, and the generic drug's entry into the market.

55. Hatch-Waxman relies on the brand name manufacturer to refrain from (a) listing patents that were improperly procured, or invalid, or not applicable to the brand name drug, and (b) bringing suit without proof that the generic applicant actually infringes a valid, enforceable, and applicable patent held by the brand name manufacturer.

56. Abuse by brand name manufacturers of the Hatch-Waxman patent protections through improper patent listing or commencement of baseless litigation improperly prevents generic competitors from bringing their less expensive bioequivalent substitute products to market. Such conduct violates antitrust law and harms purchasers of pharmaceutical products.

X. DEFENDANTS' MIRAPEX® SCHEME

Mirapex® and Pramipexole Dihydrochloride

57. Mirapex® is manufactured, marketed and sold by Boehringer throughout the entire United States. On July 1, 1997, Boehringer received approval from the FDA for Mirapex® for the treatment of Parkinson's disease. In November 2006, the FDA further approved Mirapex® for the treatment of moderate to severe Restless Leg Syndrome.

58. Currently, three companies have received either tentative or final approval from the FDA to market generic versions of Mirapex®: Mylan (tentative approval received May 8, 2007); Barr (tentative approval received October 29, 2007 and final approval received February 10, 2009); and Alembic (tentative approval received July 20, 2009). But for Defendants' unlawful conduct, one or more of these manufacturers would have offered a generic product to compete with Mirapex®.

59. The generic pramipexole product developed by Mylan, Barr and Alembic are AB-rated equivalents to Boehringer's branded Mirapex® drug, which means they are considered bioequivalent substitutes and may or must be automatically substituted for Mirapex® under certain

state laws.

60. The generic pramipexole products would be priced substantially below the price Defendants charge for Mirapex®. Because Mirapex® and its AB-rated equivalents are competitive substitutes and would be offered for a lower price, but for Defendants' misconduct, Plaintiffs and other members of the Class would have paid substantially lower prices for Mirapex® and its generic bioequivalents during the Class Period and until the effects of Defendants' misconduct ceased to be felt.

Defendants' Unlawful Scheme To Extend Its Mirapex® Monopoly

61. Although several generic drug manufacturers sought approval to market generic versions of Mirapex® in the United States, and although the products for which approval was sought did not infringe upon any valid patent, these generics have not come to market because of Defendants' unlawful and anticompetitive conduct. This conduct included: (a) obtaining the '812 Patent, which Defendants knew or should have known was invalid because the patent claimed the same compound for which Boehringer had already received patent protection; (b) listing the '812 Patent in the Orange Book; (c) seeking a five-year extension of the invalid '812 Patent; (d) suing both Barr and Mylan for violations of this known invalid patent; (e) appealing the Delaware District Court's decision finding that the '812 Patent was invalid; (f) filing an additional lawsuit in the United States District Court for the District of New Jersey, alleging infringement on its invalid '812 Patent; (g) appealing the New Jersey District Court's Order granting Mylan's motion to dismiss the litigation despite knowing that its claims were meritless; and (h) waiting until the close of the evidence and just prior to closing arguments in its baseless patent infringement litigation – nineteen (19) months after the expiration of the '086 Patent – to attempt to terminally disclaim the '812

Patent, in an attempt to avoid the inevitable judicial determination that the '812 Patent was, in fact, invalid for nonstatutory double-patenting.

62. In November 1987, Defendants applied for the '086 Patent, covering a method of treatment using tetrahydro-benzothiazoles, including the compound pramipexole.

63. While the '086 Patent application was pending, Defendants filed a second application for the '812 Patent, covering the pramipexole compound without reference to methods of treatment.

64. The '812 Patent, which applied for protection of a drug or method of treatment already covered by the '086 Patent, is a classic example of "double patenting." A patent obtained through double patenting is invalid and cannot be infringed.

65. On June 27, 1989, the U.S. Patent and Trademark Office ("PTO") approved the '086 Patent, and on December 12, 1989, the PTO approved the '812 Patent. Defendants applied for the '812 Patent despite the fact that they knew or should have known that it covered the same compound claimed in the '086 Patent and, thus, constituted invalid double-patenting.

66. Defendants improperly listed *both* patents in the Orange Book with regard to Mirapex® under the same specification and title, "Tetrahydro-Benzothiazoles, The Preparation Thereof and Their Use as Intermediate Products or as Pharmaceuticals." Defendants should not have listed the '812 Patent in the Orange Book because Defendants knew or should have known that the '812 Patent was invalid.

67. Section 156 of the United States Patent Act ("Section 156") allows for the terms of a patent to be extended where the commercial exploitation of a patented product is delayed by the applicant's seeking regulatory approval, such as by the FDA. The extension period lasts between the date the patent was granted and the date of the marketing approval. Only one, unexpired patent per

approved product may be extended.

68. On July 28, 1997, Defendants sought an extension under Section 156 for its invalid '812 Patent, which was to expire on December 12, 2006. The extension request was ultimately granted, extending the '812 Patent's expiration date until March 25, 2001.

69. Defendants chose to seek a Section 156 extension of the invalid '812 Patent and chose not to seek a Section 156 extension of the original '086 Patent.

70. On May 27, 2005, Barr filed an ANDA seeking FDA approval to market and sell a generic pramipexole 0.25 mg product that would have been bioequivalent to branded Mirapex®.

71. On June 24, 2006, Barr amended its ANDA to cover other dosages of generic pramipexole products (0.125, 0.5, 1.0 and 1.5 mg) that would also have been bioequivalent to branded Mirapex®.

72. On August 10, 2005 and September 12, 2005, Barr sent Defendants a letter notifying them that Barr had filed a Paragraph IV Certification asserting that their '812 Patent was either invalid or would not be infringed by Barr's generic product.

73. Defendants then sued Barr to enforce the '812 and the '086 Patents, even though they knew or should have known that their claims based on the '812 Patent were objectively groundless due to improper double-patenting. Defendants' motive for bringing this meritless infringement was to unlawfully extent their monopoly, thus enabling them to continue charging supra-competitive prices for Mirapex® even after their '086 Patent would have expired.

74. As mandated by the Hatch-Waxman Amendments, Defendants' infringement suit, despite being completely meritless, automatically triggered a 30-month stay thwarting approval of generic versions of Mirapex®.

75. On August 26, 2005, a second generic manufacturer, Mylan, filed its own ANDA seeking approval to market and sell generic versions of Mirapex®. Mylan informed Defendants that it had filed a Paragraph IV Certification via letter on October 26, 2005 and, within 45 days, it too was sued by Defendants for patent infringement relating to the '812 Patent.

76. Defendants' filing of an infringement lawsuit against Mylan also triggered an automatic 30-month stay from the date they received Mylan's notice letter, preventing Mylan from receiving FDA approval and launching its generic versions of Mirapex®.

77. On June 27, 2006, Defendants' original '086 Patent expired. Nonetheless, Defendants continued to pursue their patent infringement claim against Mylan and Barr to enforce its invalid '812 Patent, litigating all the way through a bench trial on the merits.

78. On March 11, 2008, at the conclusion of the bench trial – nineteen (19) months after the expiration of the '086 Patent and after subjecting the generic manufacturers to almost three years of meritless litigation – Defendants made the calculated decision to file a terminal disclaimer of the '812 Patent with the PTO. A terminal disclaimer is a binding statement made with the PTO when more than one patent has been obtained on the same invention, thus signifying that the later patent will expire at the same time as the earlier patent. When exercised properly, a terminal disclaimer can be used to cure double-patenting problems.

79. Although the proper filing of a terminal disclaimer ordinarily can cure the problems caused by double patenting, Defendants' disclaimer was improperly filed almost two years after the earlier-issued '086 Patent had expired and three years after they brought their sham patent infringement suits against Mylan and Barr.

The Delaware District Court Declares Boehringer's '812 Patent Invalid

80. On June 26, 2008, Judge Farnan of the U.S. District Court for the District of Delaware (the "Delaware District Court") issued an Opinion and Order in *Boehringer Ingelheim Int'l GmbH v. Barr Labs, Inc., et al.*, 562 F. Supp. 2d 619 (D. Del. June 26, 2008). That Opinion and Order held that Barr had shown, by clear and convincing evidence that the '812 Patent was invalid due to nonstatutory double patenting.

81. In that Opinion and Order, the Delaware District Court found that it would be impossible to practice the claims in the '086 Patent without necessarily using or forming the compounds claimed in the '812 Patent. In so finding, the court further added, "allowing Boehringer to secure a new patent on a compound which was itself specifically identified in the earlier method claims of the '086 Patent is precisely the type of monopolistic conduct the doctrine of nonstatutory double patenting was designed to prevent." *Id.* at 639.

82. The Delaware District Court further concluded that the terminal disclaimer filed by Defendants was "ineffective" because a terminal disclaimer cannot overcome an obviousness-type double patenting problem where the earlier patent has already expired. *Id.* at 631-32. In so concluding, the court expressed concern about the timing of Defendants' terminal disclaimer stating that an "unreasonable delay" in filing can extend a monopoly, which is counter to the purpose of the terminal disclaimer provision, and because "extensive delay in filing a document which may ultimately moot a double patenting issue can have harsh effects on the judicial system as a whole resulting in gamesmanship during trial, and/or a waste of the Court's and the parties' resources." *Id.* at 632 n.8.

83. Even after the Delaware District Court declared the '812 Patent invalid, Defendants continued their elaborate scheme to unlawfully maintain monopoly power in the Mirapex® market

by delaying the entry of a final judgment and appealing the court's decision to the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit"). Tellingly, in their appeal to the Federal Circuit, Defendants do not challenge the Delaware District Court's holding that the '812 Patent represented invalid double-patenting.

84. At oral argument in the Federal Circuit, two members of the panel noted that permitting a terminal disclaimer to a patent after its expiration would effectively allow patent holders to "misuse the patent during the period before the disclaimer to discourage competition," and questioned Defendants' counsel whether that should be allowed.[1]

85. On January 26, 2009, notwithstanding the decision by the Delaware District Court or the pending appeal in the Federal Circuit, Defendants filed a new complaint against Mylan in New Jersey District Court for allegedly infringing its judicially-invalidated '812 Patent with respect to a 0.75 mg pramipexole product. The sole purpose of this baseless litigation was to further delay entry of a generic 0.75 mg pramipexole product, thus enabling Defendants to squeeze even more unlawful monopoly profits out of end-consumers.

86. Not surprisingly, following oral argument, the New Jersey District Court granted Mylan's motion to dismiss from the bench in May 2009. Defendants filed a meritless notice of appeal to the Federal Circuit on June 10, 2009.

Boehringer Conspires With A Potential Competitor To Guarantee Extension Of Its Unlawful Monopoly

87. At the same time they elected to appeal the decision of the Delaware District Court, Defendants simultaneously reached a settlement with Barr, the first-filer of an ANDA application for generic Mirapex®.

88. Although the full terms of the agreement have not been made public, it has been reported that Barr agreed not to contest Defendants' appeal and not to launch a competing pramipexole product until January 2010. In return, Barr received a supply and co-promotion agreement to launch an authorized generic version of another of Defendants' drugs, Aggrenox®.

89. Barr also has not relinquished its rights to the 180-day exclusivity period as first ANDA filer for generic Mirapex®. As a result, Defendants have conspired to create a bottleneck preventing other potential generic manufacturers of pramipexole products from launching their generic versions of Mirapex® until either 75 days from the affirmance of the Delaware District Court's decision by the Federal Circuit or, if Barr launches its generic version of Mirapex® within that period, 180 days after Barr's commercial launch.

90. The conspiracy between Defendants and Barr – the first applicant to file an ANDA for generic Mirapex® - has succeeded in ensuring that generic competition in the Mirapex® market will continue to be unlawfully restrained, and Defendants will continue to receive ill-gotten monopoly profits at the expense of Plaintiffs and the other members of the Class.

XI. CLASS ACTION ALLEGATIONS

91. Plaintiffs bring this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of themselves and the following class:

> All persons and entities in the United States who purchased Mirapex® directly from one or more of the Defendants at any time from May 8, 2007 through the present and continuing until the effects of Defendants' anticompetitive conduct cease (the "Class Period"). Excluded from the class are Defendants and their parents, employees, subsidiaries, and affiliates, and federal governmental entities (the "Class").

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1 Federal Circuit Oral Argument, *available* at http://oralarguments.cafc.uscourts.gov/mp3/2009-1032.mp3.

92. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more.

93. There are numerous questions of law and/or fact common to the Class, including:

a. whether Defendants willfully obtained and/or maintained monopoly power over Mirapex® and its generic equivalents;

b. whether Defendants improperly listed the '812 Patent in the Orange Book;

c. whether Defendants' multiple actions asserting infringement of the '812 Patent were baseless;

d. whether Defendants engaged in sham litigation to prevent competition;

e. whether Defendants unlawfully excluded competitors and potential competitors from the market for the Drug;

f. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

g. whether Defendants unlawfully maintained monopoly power by delaying generic entry;

h. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

i. whether Defendants unlawfully restrained trade through their agreements with Barr;

j. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

k. the quantum of aggregate overcharge damages to the Class.

94. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

95. Plaintiffs' claims are typical of the claims of the Class because all Class members

paid overcharges, and thus suffered antitrust injury, as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

96. Plaintiffs will fairly and adequately represent, and protect the interests of, the Class. Plaintiffs have retained counsel experienced in class action and pharmaceutical antitrust litigation, and Plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

97. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Monopolization Under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2

98. Plaintiffs incorporate by reference the preceding allegations.

99. Defendants knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rated generic versions of Mirapex® and willfully to maintain their monopoly power. This scheme included, among other things:

a. Obtaining PTO approval for the '812 Patent, which Defendants knew would be invalid for "double patenting"

b. Listing the '812 Patent in the Orange Book;

c. Obtaining a Section 156 extension of the invalid '812 Patent;

d. seeking to enforce the invalid '812 Patent by filing objectively and subjectively baseless patent litigation against generic competitors;

e. filing a terminal disclaimer on the very last day of the '812 Patent trial;

f. filing a terminal disclaimer on the '812 Patent when the '086 Patent had already expired;

g. appealing its sham litigation to the Federal Circuit and filing another sham suit in the District of New Jersey seeking to enforce the invalid '812 Patent;

h. conspiring with Barr to settle Barr's claims in an anticompetitive manner that would extend Defendants' monopoly and delay generic entry; and

i. waiting until the close of the evidence and just prior to closing arguments – nineteen (19) months after the expiration of the '086 Patent – in its baseless patent infringement litigation to attempt to terminally disclaim the '812 Patent, in an attempt to avoid the inevitable judicial determination that the '812 Patent was, in fact, invalid for nonstatutory double-patenting.

100. By their scheme, Defendants intentionally and wrongfully maintained their monopoly power with respect to the Drug in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for the Drug.

101. Plaintiffs and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for the Drug than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

SECOND CLAIM FOR RELIEF

Attempted Monopolization Under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2

102. Plaintiffs incorporate by reference the preceding allegations.

103. Defendants attempted to monopolize the market for the Drug.

104. Defendants specifically intended to monopolize the market for the Drug, and took affirmative steps in furtherance of their attempt to monopolize the market for the Drug.

105. There is a dangerous probability that Defendants will succeed in the attempt to monopolize the market for the Drug.

106. As a result of this unlawful attempted maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for the Drug.

107. Plaintiffs and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for the Drug than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

THIRD CLAIM FOR RELIEF

Unlawful Restraint of Trade Under Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1

108. Plaintiffs incorporate by reference the preceding allegations.

109. Defendants' settlement agreement with Barr constitutes a contract, combination and conspiracy that substantially, unreasonably, and unduly restrains trade in the market for the Drug, and harmed Plaintiffs thereby.

110. The agreement covers a sufficiently substantial percentage of the market for the Drug to harm competition.

111. Defendants are *per se* liable for the creation, maintenance, and enforcement of the

agreement with Barr.

112. Alternatively, Defendants are liable for the creation, maintenance, and enforcement of the agreements under a "quick look" and/or rule of reason standard.

113. There is no legitimate, procompetitive business justification for the agreement that outweighs its harmful effect. Even if there were some conceivable such justification, the agreements is broader than necessary to achieve such a purpose.

114. Plaintiffs and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for the Drug than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

FOURTH CLAIM FOR RELIEF

Conspiracy to Monoplize Under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2

115. Plaintiff incorporates by reference the preceding allegations.

116. Through their agreement, Barr and Defendants conspired to maintain and enhance Defendants' monopoly power in the relevant market.

117. Barr and Defendants knowingly and intentionally entered into their agreement.

118. Barr and Defendants specifically intended that their agreement would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

119. Barr and Defendants each committed at least one overt act in furtherance of their conspiracy.

120. As a result of this unlawful conspiracy to monopolize, Plaintiff and members of the Class paid artificially inflated prices for the Drug.

121. Plaintiff and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for the Drug than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiff and the Class are the proper entities to bring a case concerning this conduct.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following:

A. Judgment in their favor and against Defendants, jointly and/or severally, for damages representing the overcharges paid by Plaintiffs and the other members of the Class, trebled;

B. Pre- and post-judgment interest; and

C. Costs of suit, including reasonable attorneys' fees.

XIV. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: August 17, 2009

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